

## **ATTACHMENT A**

# **COMPLIANCE AGREEMENT BETWEEN BETH ISRAEL DEACONESS MEDICAL CENTER AND THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**

This Compliance Agreement ("Compliance Agreement") is entered into between the Beth Israel Deaconess Medical Center ("BIDMC") and the United States Department of Health and Human Services ("HHS"). Pursuant to this Compliance Agreement, BIDMC agrees to undertake the compliance obligations outlined below.

### **I. Preamble**

BIDMC has implemented and shall maintain a Compliance Program ("Program") designed to prevent fraud, false statements or misexpenditure of funds related to HHS grants, contracts and cooperative agreements ("grants and contracts") by BIDMC, its officers, faculty, and employees. The Program shall be maintained so as to ensure, to the greatest extent reasonably possible, that BIDMC and each of its officers, faculty, and other relevant employees maintain the integrity required of a recipient of federal funds, and that BIDMC is in compliance with all laws and regulations applicable to such awards and with the terms of this Compliance Agreement set out below.

The Program is part of BIDMC's Corporate Compliance Program as described in the following BIDMC documents: Compliance Program Policy Manual for Research Activities; Corporate Compliance Program Description; Corporate Integrity Program Policy Manual; Code of Conduct; Policies and Procedures for the Management and Administration of Sponsored Projects and Compliance Program - Guiding Principles for Researchers. These documents are incorporated by reference to this Compliance Agreement.

## **II. Terms and Conditions**

The period of future compliance obligations assumed by BIDMC under this Compliance Agreement shall be three (3) years from the date of execution of this Compliance Agreement.

BIDMC agrees to implement or continue the following measures within ninety (90) days of the date of execution of this Compliance Agreement, unless otherwise specified below.

### **A. BIDMC Compliance Officer and Committee**

BIDMC has established and shall continue to maintain a Director of the Office of Business Conduct, as described in Section I. of BIDMC's Corporate Compliance Program Description, who shall be appointed by the President and report to the President and the Board of Trustees. BIDMC shall maintain its Compliance Oversight Committee and coordinate compliance activities with respect to grants and contracts under the direction of the Director of the Office of Business Conduct, the Vice President of Science and Technology and the Office of Research Finance as provided in BIDMC's Compliance Program Policy Manual for Research Activities.

### **B. Audit Requirements**

In addition to the single audit requirements contained in OMB Circular A-133, the Internal Audit office of BIDMC shall conduct, on an annual basis, a comprehensive audit of randomly selected grants and contracts as provided for in Section 3. of the BIDMC Compliance Program Policy Manual for Research Activities. The audit shall review BIDMC's compliance with all applicable federal laws and regulations regarding the use and expenditure of HHS grant and contract funds, including the uniform administrative requirements contained in 45 C.F.R. Part 74, the Federal Acquisition Regulations, regulations governing grants for research projects in 42 C.F.R. Part 52 and cost principles contained in 45 C.F.R. Part 74, Appendix E. Such audits shall be performed with respect to each Department of BIDMC that receives or has oversight responsibility with respect to HHS grants and contracts and shall be conducted in accordance with Generally Accepted Auditing Practices. Special attention shall be devoted to internal controls to ensure compliance with HHS requirements, including the certifications made on applications, progress reports and other reports related to grants or contracts.

If other reviews conducted at BIDMC reveal situations that might constitute or indicate noncompliance with HHS requirements for HHS grants and contracts, the results of such reviews shall be provided to the Director, Office of Business Conduct.

**C. Annual Written Reports**

BIDMC will annually provide HHS with a copy of all written reports and findings of the internal audit described in section II.B. of this Compliance Agreement. BIDMC will also annually provide HHS with a written report of the corrective actions that BIDMC has undertaken as a result of any deficiencies that were discovered by the internal audit or by audits or reviews conducted pursuant to OMB Circular A-133 or by other audits or reviews. Such reports shall be due one year after execution of this Compliance Agreement and for each of the two years thereafter. This report on BIDMC's corrective actions will include a certification by BIDMC's Director of the Office of Business Conduct that all deficiencies found have been addressed to ensure BIDMC's compliance with all requirements of federal law, regulation, and this Compliance Agreement. HHS may request additional corrective action if it believes that BIDMC's actions are not adequate to ensure compliance with federal requirements.

All audit workpapers or other supporting documents for audits or reviews of federal compliance relating to HHS grants and contracts and undertaken pursuant to this Compliance Agreement shall be made available to HHS upon request.

Any violations discovered during any audits or review shall be reported immediately to HHS and remedied within sixty (60) days of identification by BIDMC. BIDMC will report its findings concerning the material violation, its actions to correct such material violation, and any further steps BIDMC plans to take to address such material violation and prevent it from recurring in the future. A material violation is one which has a significant, adverse impact on HHS research or administration of projects supported by HHS grants or contracts.

**D. BIDMC's Compliance Policy**

BIDMC has implemented and shall maintain written policies regarding its commitment to ensure compliance with all laws and regulations related to the receipt of federal grants and contracts. These policies shall be adopted by the Board of Directors and distributed to relevant employees as defined in Paragraph II.E. They shall be included as part of the annual training and shall be included as

part of the annual report to HHS. Such policies shall be updated to reflect any changes in BIDMC's policy or practices. BIDMC's compliance policy shall include disciplinary procedures for dealing with employees who knowingly fail to meet the terms and conditions of federal grants or contracts.

**E. Education and Training**

BIDMC has implemented and shall maintain an education and training program as described in Section 2 of BIDMC's Compliance Program Policy Manual for Research Activities. The education and training program shall be designed to ensure that each officer or other relevant employee is aware of all applicable laws and regulations and standards of conduct that such individual is expected to follow in reporting to HHS on grants and contracts, and the consequences both to the individual and BIDMC that will ensue from any violation of such requirements. Relevant employees are those employees described in Section 2 of BIDMC's Compliance Program Policy Manual for Research Activities and those individuals with a role or responsibility in the receipt of, or application for, HHS grants or contracts and those individuals who conduct projects supported by HHS grants or contracts. Each officer and other relevant employee shall receive at least one hour of initial training that shall include a discussion of the contents of BIDMC's Compliance Agreement, and shall receive additional training of at least one hour on an annual basis. A schedule and topic outline of the training shall be included in the annual report submitted to HHS pursuant to this Compliance Agreement.

**F. Confidential Disclosure Program**

BIDMC has established and shall maintain a confidential voluntary reporting mechanism, as described in Section 6 of BIDMC's Corporate Compliance Program Description, enabling employees to disclose anonymously any practices or procedures, deemed by the employee to be inappropriate, to BIDMC's Office of Business Conduct. BIDMC shall make the confidential voluntary reporting mechanism known to employees as part of his or her training. BIDMC shall, as part of the confidential voluntary reporting mechanism, require the internal review of any such credible disclosure and ensure that proper follow-up is conducted. BIDMC shall include in its annual compliance report to HHS a summary of communications concerning inappropriate conduct relating to HHS grants and contracts under the confidential voluntary reporting mechanism, and the results of any internal review and follow-up of such disclosures.

### **III. HHS Inspection, Audit and Review Rights**

In addition to any other right that HHS has pursuant to 45 C.F.R. 74.53, FAR 4.703, or other authority, HHS or its duly authorized representative(s) may examine and copy BIDMC's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) BIDMC's compliance with the terms of this Compliance Agreement; (b) BIDMC's conduct in its dealing with HHS; and (c) BIDMC's compliance with any HHS requirements. The documentation described above shall be made available by BIDMC at all reasonable times for inspection, audit and/or reproduction. Furthermore, for purposes of this provision, HHS or its authorized representative(s) may interview any BIDMC employee who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and HHS. Employees may elect to be interviewed with or without a representative of BIDMC present.

### **IV. Dealing with Debarred or Suspended Persons**

BIDMC shall implement, and make appropriately known including as part of its education and training program, a written internal operating policy that BIDMC shall not knowingly hire, or enter into a consultant contract, with or without pay, an individual who is listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for federal programs in a capacity involving responsibility for, or involvement with, the receipt of federal grants, contracts, or other benefits. As part of carrying out the policy, BIDMC shall make reasonable inquiry into the status of any potential employee or consultant. Such reasonable inquiry shall include, at a minimum, review of the GSA List of Parties Excluded from Federal Procurement and Non-Procurement Programs (available through the Internet at <http://www.arnet.gov/epl>) and the HHS/OIG Cumulative Sanction Report (available through the Internet at <http://www.dhhs.gov/progorg/oig>).

As to individuals who become excluded, suspended, convicted or are proposed for debarment or exclusion, while they are employed by, or under a consultant contract with, BIDMC, BIDMC will remove such employees from responsibility for, or involvement with, the receipt of federal grants, contracts, or federal health care programs reimbursement. BIDMC shall also remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care

programs. BIDMC shall notify HHS of each such personnel actions taken and the reasons therefore, within fifteen (15) days of the action.

**V. Breach and Default Provisions**

In the event that HHS believes BIDMC has breached one or more of its obligations under the Compliance Agreement, HHS shall notify BIDMC of the alleged breach by certified mail, specifying the nature and extent of the alleged breach. BIDMC will have thirty (30) days from receipt of the notice: (a) to cure said breach; or (b) otherwise satisfy the government that (1) it is in full compliance with this Compliance Agreement or (2) the breach cannot be reasonably cured within 30 days, but that BIDMC has taken action to cure the breach and is pursuing such action with diligence.

If, at the end of the thirty day period described above, HHS determines that BIDMC continues to be in breach of one or more of its obligations under this Compliance Agreement, HHS may, in writing and by certified mail, declare BIDMC to be in default and initiate proceedings to undertake appropriate administrative action, including suspension or debarment. If BIDMC is debarred based upon breach of the Compliance Agreement, and in the event BIDMC fully cures the material breach or otherwise satisfies HHS, it will be promptly reinstated, retroactive to the date of cure.

**VI. Costs of Additional Audits**

In addition to the obligations assumed by BIDMC under this Compliance Agreement and as described above, if HHS determines that an independent audit or review is needed to determine whether or to the extent to which BIDMC is complying with its obligation under this Compliance Agreement, BIDMC agrees to pay for the reasonable cost of any such audit or review by HHS or another independent entity.

**VII. Modification**

BIDMC and HHS agree that any modification to this Compliance Agreement shall not be effective until a written amendment is signed by the signatories to this Compliance Agreement or by institutional representatives duly authorized to execute such amendment.

# **VIII. Notifications and Submission of Reports**

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

## **Department of Health and Human Services:**

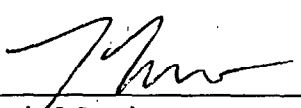
Terrence J. Tychan  
Deputy Assistant Secretary for Grants and Acquisition Management  
U.S. Department of Health and Human Services  
Humphrey Building  
Room 517D  
200 Independence Avenue, S.W.  
Washington, D.C. 20201  
Phone: (202) 690-6901

## **Beth Israel Deaconess Medical Center:**

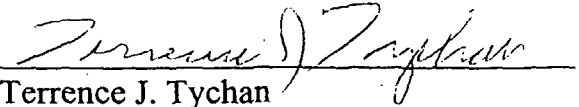
Leon Goldman, M.D.  
Director, Office of Business Conduct  
Beth Israel Deaconess Medical Center  
330 Brookline Avenue  
Boston, MA 02215  
Phone: (617) 667-4147

IN WITNESS WHEREOF, the parties affix their signatures.

FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

  
\_\_\_\_\_  
Lewis Morris  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
Department of Health and Human Services

3/17/99  
Date

  
Terrence J. Tychan  
Deputy Assistant Secretary for Grants and  
Acquisition Management  
Department of Health and Human Services

2-18-99  
Date

FOR BETH ISRAEL DEACONESS MEDICAL CENTER

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By: Herbert Kressel, President

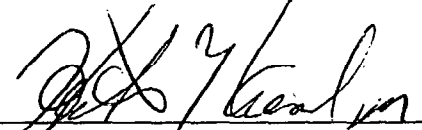
\_\_\_\_\_  
Date



\_\_\_\_\_  
Terrence J. Tychan  
Deputy Assistant Secretary for Grants and  
Acquisition Management  
Department of Health and Human Services

\_\_\_\_\_  
Date

FOR BETH ISRAEL DEACONESS MEDICAL CENTER

  
\_\_\_\_\_  
By: Herbert Kressel, President

3/18/99  
Date